REMARKS

I. Status of the Claims

Claims 1-69 were originally filed. Subsequently, claims 11-21 and 24-69 were canceled. Upon entry of the present amendment, claims 9 and 10 are further canceled. Claim 1 is amended to recite that the claimed nucleic acid encodes a polypeptide comprising an amino acid sequence having at least 80% sequence identity to SEQ ID NO:4. Claims 2 and 4 are amended to recite this percentage identity to be 90% and 95%, respectively. Support for these percentage sequence identities can be found in the specification, *e.g.*, on page 16, lines 12-17. Claims 4, 7, and 8 are further amended to improve clarity. Thus, no new matter is introduced by this amendment.

II. Claim Rejections

A. 35 U.S.C. §101

In the Office Action mailed May 4, 2005, the rejection of claims 1-10, 22, and 23 under 35 U.S.C. §101 for alleged lack of patentable utility was maintained. Applicants respectfully traverse the rejection for reasons already set forth in the previous response filed on February 1, 2005, as well as in the concurrently filed declaration under 37 C.F.R. §1.132 by Dr. McCormack.

In his declaration, Dr. McCormack attested that there are many instances where modulation of an ion channel can be useful for treating a disease, even though the disease may not be directly caused by the ion channel. He used calcium channel blockers and treatment of hypertension as an example to illustrate this point. In the Office Action mailed May 4, 2005, the Examiner dismissed Dr. McCormack's statement by contending that potassium channels are a different class of ion channels from calcium channels and that the manner in which calcium channels are modulated is not necessarily predictive of the therapeutic use of potassium channels. The Examiner further argued that because there are many different potassium channels and there is no nexus between the claimed Slo potassium channel and therapeutic use through the specific channel, the claimed invention has no substantial utility.

Applicants respectfully disagree. While potassium channels are undoubtedly a type of ion channels with some features distinct from that of calcium channels, potassium channels are nonetheless ion channels involved in regulating important physiological events and processes just like calcium channels. In other words, these two classes of ion channels still share many common characteristics such that one of skill in the art would reasonably believe that modulating their activity can be used in a similar fashion for therapeutic purposes. The notion that a given potassium channel, such as the claimed Slo4 channel, need not be in a specific causal relationship with a disease to be useful for treating the disease, also alludes to the potential use of more than one potassium channel as a therapeutic target for treating a disease. This is what Dr. McCormack has established by way of his declaration (see paragraph 8 of the declaration). Applicants do not believe that it is appropriate to simply disregard this declaration offered by a person of skill in the art, when such disregard is unsubstantiated by either objective reasons or scientific evidence.

Applicants reiterate that no *prima facie* showing of lack of patentable utility has been established, particularly in light of Dr. McCormack's declaration. The withdrawal of the utility rejection is therefore respectfully requested.

B. 35 U.S.C. §112, First Paragraph

The Examiner also maintained the rejection of claims 1-10, 22, and 23 under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. This enablement rejection was based on the alleged lack of patentable utility of the claimed invention. In light of the forgoing discussion, Applicant believes that this utility-based enablement rejection should be properly withdrawn.

C. 35 U.S.C. §102

Claims 1-3, 7, 8, 10, 22, and 23 were rejected under 35 U.S.C. §102(e) for alleged anticipation by Curagen Corporation (WO 01/90366). Claims 1-3, 6-10, 22, and 23 were also rejected under 35 U.S.C. §102(e) for alleged anticipation by Wei *et al.* (US 2002/0048787). Moreover, claims 1, 3, 7, 8, 10, 22, and 23 were rejected under 35 U.S.C. §102(b) for alleged

anticipation by Salkoff *et al.* (WO 99/20754). Applicants respectfully traverse the rejection, particularly in light of the present claim amendment.

To anticipate a pending claim, a prior art reference must provide, either expressly or implicitly, each and every limitation of the pending claim. MPEP §2131. The pending claims are directed to an isolated nucleic acid encoding a Slo4 polypeptide comprising an alpha subunit of a Slo potassium channel. This Slo4 polypeptide has the following properties: (i) it forms, with at least one additional alpha subunit, a potassium channel comprising the characteristic of voltage-gating; and (ii) it comprises an amino acid sequence having at least 80% sequence identity to SEQ ID NO:4.

In contrast, none of the three cited references disclose an amino acid sequence having an 80% or higher sequence identity to SEQ ID NO:4. More specifically, the relevant sequence in the Curagen reference is SEQ ID NO:2618, which is an amino acid sequence of 104 residues. Even if assuming that all of the 104 amino acids are identical to their corresponding residues in SEQ ID NO:4 of the present application, which is 1135 amino acids in length, SEQ ID NO:2618 of Curagen can have no more than 10% sequence identity to SEQ ID NO:4 of this application. As characterized by the Examiner, the relevant amino acid sequences disclosed in Wei *et al.* (SEQ ID NO:2) and in Salkoff *et al.* (Slo3 amino acid sequence) are 75.1% and 22% identical to SEQ ID NO:4 of this application, respectively (see page 5 of the Office Action mailed May 4, 2005). Thus, no disclosure of an amino acid sequence having at least 80% sequence identity to SEQ ID NO:4 of the present application can be found in the three cited references. None of the three references can therefore anticipate the pending claims. Accordingly, the withdrawal of the anticipation rejections is respectfully requested.

III. Priority

In the Office Action of May 4, 2005, the Examiner again contended that USSN 60/249,112, to which the present application claims priority, does not adequately support claims 1-10, 22, and 23 of this application. The Examiner's position, as indicated by this and the previous Office Action, is that the priority document is not enabling due to the alleged lack of patentable utility of the invention described. As already pointed out in Applicants' last response,

USSN 60/249,112 fully and accurately discloses the polynucleotide and polypeptide sequences for human Slo2 and Slo4 (*see, e.g.*, pages 74-76 of USSN 60/249,112); describes the characteristics of the potassium channels (*see, e.g.*, Examples 1 and 2 on pages 65-73); and asserts their utility as a therapeutic target for treating neurological or other conditions (*see, e.g.*, page 11). This application thus provides full support for the present application in the substance disclosed. As far as utility-based enablement is concerned, Applicants believe that the above discussion has already properly established utility under 35 U.S.C. §101 for the claimed invention, the provisional application therefore does not fail to enable for utility reasons. The withdrawal of the objection to the priority claim is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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